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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,927	09/12/2003	William J. Wechter	LOMACEN.015C4	7323

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,927	WECHTER, WILLIAM J.	
	Examiner	Art Unit	
	Raymond J Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date November 17, 2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

CLAIMS 1-16 ARE PRESENTED FOR EXAMINATION

Applicant's Information Disclosure Statement filed November 17, 2003 has been received and entered into the application. As reflected by the attached, completed copy of form PTO-1449 (4 pages), the cited references have been considered.

Claim Rejection - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In present claims 1 and 2, the metes and bounds of the subject matter for which applicant seeks patent protection by the term "enriched" is unclear. The conventional meaning of enriched is to add to or to make richer. However, it is not seen how this could hold true when a composition of 100% gamma-tocopherol is contemplated (present claim 8). A 100% pure gamma-tocopherol composition is not a composition that is gamma-tocopherol enriched.

Double Patenting

Non-Provisional

I Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12 and 33-42 of U.S. Patent No. 6,242,479 (Wechter, cited by Applicant). Although the conflicting claims are not identical, they are not patentably distinct from each other because given that the percentages of the patented claims for

gamma-tocopherol are those of the present claims, the requirement in the present claims that the tocopherols composition is "enriched" with gamma-tocopherol is deemed to not represent a patentable distinction.

Also, while in patented claim 12 "a neurological disease" is required while the present claims encompass specific neuro-ischemic conditions, such is not seen to a patentable distinction because the term "a neurological disease" is broad and would have encompasses the specific neurological diseases as presently claimed.

Finally, in present claim 2, it is required that a gamma-tocopherol be administered while in the patented claims, no such requirement is set forth. This, however, is not seen to be a patentable distinction because once administered, the gamma-tocopherol of the patented claims would be metabolized and thus the gamma-tocopherol of the patented claims is functioning as a pro-drug for a gamma-tocopherol metabolite and thus renders obvious the presently claimed subject matter.

II Claims 1-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,048,891 (Wechter, cited by Applicant). Although the conflicting claims are not identical, they are not patentably distinct from each other because in present claim 2, it is required that a gamma-tocopherol be administered while in the patented claims, no such requirement is set forth. This, however, is not seen to be a patentable distinction because once administered, the gamma-tocopherol of the patented claims would be metabolized and thus the gamma-tocopherol of the patented claims is functioning as a pro-drug for a gamma-tocopherol metabolite and thus renders obvious the presently claimed subject matter.

Also, while not all of the specific percentages of gamma-tocopherol or a metabolite thereof as presently claimed are specifically claimed in the patented claims, such percentages are encompassed by the patented claims because in patented claim 1, it is set forth that "at least 50% of said tocopherols [are] [gamma]-tocopherol".

Finally, while in patented claim 7 "ischemia" is required while the present claims encompass non-cardiovascular ischemic conditions, such is not seen to a patentable distinction because the term "ischemia" is broad and would have encompasses the specific non-cardiovascular ischemic conditions as presently claimed.

Provisional

I Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/661,336. Although the conflicting claims are not identical, they are not patentably distinct from each other because in the present claims, the term "non-cardiovascular tissue ischemic condition" would clearly encompass the cerebral ischemic condition of the co-pending claims. Also, in the copending claims (e.g., claim 4) a specific gamma-tocopherol metabolite is set forth, i.e., 6-hydroxy-2,7,8-trimethylchroman-2-propanoic acid (LLU-α) while in the present claims, (e.g., claim 2) "a gamma-tocopherol metabolite" is set forth which would have encompassed the specific metabolite of the co-pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

II Claims 1-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12-24 and 26-32 of

copending Application No. 10/372,510. Although the conflicting claims are not identical, they are not patentably distinct from each other because the term "non-cardiovascular tissue ischemic condition" in the present claims would clearly encompass the ischemic conditions of the co-pending claims which are not cardiovascular related. Also, in the copending claims (e.g., claim 20) a specific gamma-tocopherol metabolite is set forth, i.e., 6-hydroxy-2,7,8-trimethylchroman-2-propanoic acid (LLU-α) while in the present claims, (e.g., claim 2) "a gamma-tocopherol metabolite" is set forth which would have encompassed the specific metabolite of the co-pending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

May 10, 2004